

STATE OF WASHINGTON DEPARTMENT OF HEALTH Olympia, Washington 98504

WASHINGTON STATE BOARD OF PHARMACY

MEETING AGENDA March 1, 2007

Department of Health CenterPoint Corporate Park 2nd Floor – Room 1 20435 72nd Avenue Kent WA 98032

CONVENE

Chair Rebecca Hille convened the meeting at 9:08 a.m. on March 1, 2007.

Board Members present:

Gary Harris, RPh – Vice Chair George Roe, RPh Rebecca Hille, Chair Rosemarie Duffy, RN Susan Teil-Boyer, RPh Vandana Slatter, PharmD

Staff Members present:

Lisa Salmi, Acting Executive Director Tim Fuller, Pharmacy Consultant Andy Mecca, Pharmacy Consultant Grace Cheung, Chief Investigator Joseph Honda, Pharmacist Investigator Doreen Beebe, Program Manager

Staff Member Absent:

Joyce Roper, Assistant Attorney General

CONSENT AGENDA

- **1.2** Pharmacy & Other Firm Application Approval
 - o New & Closed Pharmaceutical Firms 12/22/2006 thru 02/11/2007
- **1.4** Pharmacy Tech Training Program Approval
 - o Diane Goncalves NW College in West Covina CA
 - o Svetlana Chuvashove The Perm State Pharmaceutical Academy in Perm, Russia
 - Olga Perminova The Perm State Pharmaceutical Academy in Perm, Russia
- 1.5 Collaborative Drug Therapy Agreement Acceptance
 - o Auburn Community Health Centers of King Co Various Pharmacists
 - Tom Roe & Various Pharmacists Warfarin Dosing
 - o Tom Roe & Various Pharmacists Vancomycin

- o Tom Roe & Various Pharmacists Antimetic Dosing
- o Tom Roe & Various Pharmacists Tapering Opioids for Pediatric Patients
- o Tom Roe & Various Pharmacists Pain Management
- **1.8** Board Minute Approval January 26, 2007

Items 1.1 – Pharmacist License Application; 1.3 – Pharmacy Technician Application Approval; 1.6 Automated Drug Dispensing Device Acceptance; and 1.7 Sample Distribution Requests were deleted from the consent agenda. **MOTION**: George Roe moved that the Board approve 1.2, 1.4, 1.5, and 1.8 of the consent agenda. Susan Teil-Boyer second. **MOTION CARRIED 6-0.**

REPORTS

Acting Executive Director

Lisa Salmi reported:

- February 6, 7, and 8 the Board held a hearing to consider *Statement of Charges* with a notice of *Intent to Deny* the application of BioMed Inc. The Board members participating on the panel included Asaad Awan, Rebecca Hille, George Roe, Gary Harris and Protem members Don Williams and Leon Alzola.
- Performance Auditors continue to meet with credentialing and investigative staff. The auditors are expected to complete interviews at the end of March. The final report is due to the legislature in July.
- Staff continuing to be participating in focus groups with the new licensing program eLicense. Doreen Beebe and Janelle Teachman were selected to attend intensive training the third week in March. They will then become the primary trainers on the system for Section Four.
- Grace Cheung, Judy Haenke (Program Manager for Veterinary and Vision Programs) and Lisa Salmi are involved in the Health Systems Quality Assurance (HSQA) organizational review workgroups looking at different functional areas. Staff is involved with three of the five workgroups -Inspection & Compliance, Customer Service, Health Professions and Facilities, Legal Services and Community Health Services.
- Proposed rules regarding Pharmacies' and Pharmacists' Responsibilities filed with the Code Reviser's office on February 20th. Rules hearing is scheduled for March 29 and 30 in Renton.
- February 28th was the first legislative cut-off. March 14 is the last day to consider bills in the house of origin.
- Methamphetamine Workgroup will meet on March 21st. The Workgroup is scheduled to present its findings to the Legislature in November 2007. Current legislation may potentially change the scope of this workgroup.
- Upcoming meetings: HPQA Annual Leadership Conference May 14 in Seattle, HPQA Annual Board/Commission and Committee Conference -September 27 – 28 in Renton and Annual Citizens Advocacy Center – October 31 – November 2 in Seattle (targeted for public members). The Department of Health is discussing plans to hold an Open House for key legislative leadership in the Fall of 2007 to showcase different activities of the department.
- Tim Fuller and Lisa Salmi participated in opening session of the Pharmacists Day in the Legislature on February 16th. Speakers included: Senator Parlette and Mary Selecky.

Board Member Reports:

Dan Connolly, newest member of the Board, appointed by the Governor on February 16, 2007, has worked as a pharmacist for 40 years in a variety of practice settings - independent community pharmacy, King County Hospital, Pay & Save Pharmacy and Bartell Drugs the last 20 years. Mr. Connolly will be attending the Governor's Gubernatorial New Member Orientation on March 5th.

Gary Harris spoke briefly about his task to encourage pharmacists to sign-up for the Board's electronic newsletter. The electronic list will also provide a mechanism to disseminate information to pharmacists more effectively. http://listser.wa.gov/archives/wsbop-newsletter.html

Rebecca Hille, Madame Chair, announced that Vandana Slatter is unable to attend the University of Utah School of Alcoholism and Drug Dependencies June 24 – 29, 2007. Therefore, Gary Harris and Board Investigator Kelly McLean will attend.

Rebecca Hille and Tim Fuller reiterated the Board's 2007 – 2009 Goals

- Complete Rule Process for the Top Five Rule Priorities
 - 1. Correctional Facilities
 - 2. Pharmacy Technician National Standardized Examination
 - 3. Extended Care Facilities Destruction of Controlled Substances
 - 4. Soma CSA
 - 5. Update Wholesalers Rules
- Increase Communication & Awareness to the Profession and Public
 - 1. Acknowledge Board's Accomplishments
 - 2. Communicate Board's Mission & Vision
 - 3. "Frequently Asked Questions"
 - 4. For Public Safety Retaining Pharmacist Investigators
- Establish Continuing Education Credit for Attending Board Meetings
- Communicate Information via Email to Washington Pharmacists

Consultant/Investigator Pharmacists

Tim Fuller reported

- Osteopathic Physician Assistants proposed changes to ability to prescribe controlled substances. Currently Osteopathic PA's are permitted to prescribe Schedules III V. The proposed rule will allow those practitioners that pass a National certification examination within the next year to prescribe Schedule II V. Those that do not take or pass the examination will continue to have prescriptive authority for Schedule III V. Note: Mr. Fuller will research whether the department will issue an alternative designator that would identify those with increased authority.
- Attended University of Washington Annual Visiting Committee Day (member of Dean's Visiting Committee for the School of Pharmacy). Sid Nelson, School of Pharmacy Dean, was nationally recognized as Dean of the Year.
- Attended Washington State Pharmacy Association's New Laws New Drugs Annual presentation.
- Attended WSPA Mid-year Conference and presented to the pharmacy technician roundtable speaking about the national certification examination and other rules involving technicians.

Andy Mecca reported:

- Provided a presentation on Frequently Asked Questions at the WSPA Mid-year Conference.
- Attended the Washington State Patient Safety Coalition planning session on February 16. Discussions focused on medication reconciliation and implementing a program to get patients to carry cards identifying current medication regiments and how pharmacists or providers may play a role.
- Stan Jeppesen and Andy Mecca will be participating with the University of Washington for the annual Multistate Jurisprudence Examination review.

Chief Investigator

Grace Cheung distributed copies of the Chief Investigator's report which highlighted Board Investigators' activities for January and February – Inspection and investigation statistics, educational projects, PH:ARM project, and the UW School of Pharmacy Admissions Committee.

Investigators' Meeting

- March 8 Susan Teil-Boyer
- June 6/7 Vandana Slatter Tentative
- September 12/13 George Roe
- December 5/6 unassigned

Program Manager

Doreen Beebe reported:

• Rosemarie is schedule to attend the Governor's Gubernatorial New Member Orientation on March 5, 2007 and Vandana Slatter will be attending in September.

PRESENTATIONS

<u>Providence Centralia Proposal to Utilize Remote Order Processing.</u> The Board considered a proposal from Providence Centralia to utilize Providence Everett Medical Center for after hours remote order processing. The proposal meets the Board's guidelines for remote order processing.

• Note: Provide copy of protocol to area investigator.

Pharmacist Manager Linda Higginson indicated that the volume of medication order is approximately 20 per night. Ms. Higginson stipulated that remote order processing is provided by Providence Everett Medical Center seven day a week from 12:00 a.m. until 6:00 a.m.

ACTION: Susan Teil-Boyer moved that the Board approve the proposal by Providence Centralia to use remote order processing with its sister facility Providence Everett Medical Center. Rosemarie Duffy second. **MOTION CARRIED**. 6-0.

<u>ExcelleRx</u>, <u>Inc.</u> requests for the <u>Use of Automated Drug Distribution Device</u> is postponed until a future meeting. This agenda item was tabled at the October meeting to allow representatives from ExcelleRx, Inc. to provide additional information.

<u>Frequently Asked Questions Presentation.</u> Andy Mecca presentation highlighted questions frequently asked by callers contacting the Board office regarding a variety of issues. Staff and callers are often challenged when the answers are not a simple yes or no and must rely on the

pharmacist's professional judgment. Mr. Mecca explained that pharmacies share the Board's mission to promote and protect public health and safety. The process of dispensing prescriptions, similar to the disciplinary process, is individual and is ultimately designed to protect patient health.

Mr. Mecca reviewed frequently asked questions relating to:

- Prescriptive authority ARNP's, Optometrists, Naturopathic Physicians, Dentists, Out-of-State and Canadian Practitioners
- DEA Numbers
- HPQA Practitioner Look-up Verification
- Prescriptions from U.S. Territories
- Practitioners prescribing for oneself and family
- Scope of Practice
- Off Label Use
- Controlled Substance Inventory
- Prescription Records
- Prescription Information, Labels, and Expiration Dates
- Office Use Prescriptions
- Electronic Prescriptions
- References on-line or hardcopy
- Pharmacist Responsible Manager Responsibilities
- Faxing, Changing, and Emergency Fills of Controlled Substances
- Suboxone, Methadone

The goal for pharmacists is to take care of the patient and use good judgment. Mr. Mecca strongly encourages the documentation of your decisions as deemed necessary.

Telepharmacy proposal from Community Health Clinics of King County (CHCKC)

Tim Fuller provided background on a new community health services in King County. Due to transportation challenges CHCKC is proposing to use telepharmacy services to meet the needs of its patients.

Mr. Fuller summarized for the new Board members the history of Board approved telepharmacy models, beginning with Community Health Association of Spokane (CHAS).

David Rose, Pharmacy Services Manager for Kent Community Health Services briefed the Board on the proposed remote dispensing process and explained the pharmacist's oversight. The program uses automated drug distribution devices. No service is provided from the remote site in times of power outages; patients are directed to the main pharmacy or other alternatives.

- Main/supervising pharmacy located in Kent
- Pre-filled medication will be labeled with barcode, drug name, strength, lot number, expiration date and number of doses
- Dispensing label will only print if the barcode indicates the medication is correct
- Once medication is verified by pharmacist the patient is counseled by pharmacist via the webcam
- Seven clinics through King County with two contract pharmacies to fill 30 medications on behalf of the clinics
- Initial target 35 to 40 new prescriptions per day no refills

- Refills are process by the main pharmacy for pick-up or delivery to the clinic or by mail to the patient
- Provide access to patients
- CHCKC offers medications for free or sliding scale for indigent, working poor or underinsured patients
- Formulary list updated monthly

Note: Susan Teil-Boyer asked that the Board conduct a site visit the next time the Board meets in Kent to observe the process.

ACTION: Susan Teil-Boyer moved that the Board approve the SeaTac telepharmacy proposal by CHCKC. Rosemarie Duffy second. Dan Connolly recused himself from the vote. **MOTION CARRIED**. Susan Teil-Boyer, Rosemarie Duffy, Vandana Slatter and Gary Harris voted in favor and George Roe opposed. Vote 4 - 1.

Accreditation of Schools/Colleges of Pharmacy.

ACTION: George Roe moved that the Board approve the accreditation of Colleges and Schools of Pharmacy of Colleges and Schools of Pharmacy adopted through the American Council on Pharmaceutical Education (ACPE) as the official list of accredited professional pharmacy programs. Vandana Slatter second. **MOTION CARRIED**. 6-0.

<u>Election of Officers</u>. Robert's Rules of Order directs the Vice-Chair, Rebecca Hille, to assume the role of Chair and a nomination for Vice-Chair was accepted. **ACTION**: George Roe nominates Gary Harris as Vice-Chair. Rosemarie Duffy second. Mr. Harris accepted the appointment. **MOTION CARRIED**. Unanimous vote in favor.

Official Delegate to the 2007 National Association of Boards of Pharmacy Annual Meeting. **ACTION**: Susan Teil-Boyer moved that the Board name the Chair the official voting delegate and the Vice-Chair the alternate to attend the NABP Annual Meeting. Rosemarie second. **MOTION CARRIED**. 6-0.

EXECUTIVE SESSION

The Board adjourned at 12:00 p.m. for the Executive Session to discuss personnel issues and pending litigation.

The Board reconvened at 1:00 p.m. for presentation of Agreed Orders.

DISCUSSION

2007 Legislation Update

Lisa Salmi updated the Board on 2007 legislation, but cautioned that there may have been changes since the report was prepared.

2SHB1103 – shift authority to the Secretary of Health to initial mandatory investigation when there is a pattern of conduct. Boards and Commission should provide consultation and assistance as requested by the Secretary when reviewing complaints. It also requires the Secretary to ensure that Board and Commissions are actively involved in an investigation if the allegation involves standard of practice or needs clinical expertise. (Includes portions of other legislation HB1101-

sanction guidelines, HB1100 background checks and HB1104 – requires a chaperon during gynecological exams.)

- Requires boards and commissions to develop continuing competency programs.
- Requires boards and commissions to submit a report as an adjunct to the annual report generated by the Secretary.
- Permits members of boards and commission to communicate directly with members of the Legislature regarding board and commission work, even if their position contradicts the department's official position.
- Allows the Secretary to spend unappropriated funds in the health professions account to meet unanticipated costs when revenue exceeds more than 15% of department's six year projection.
- Modifies the process to be used for the development of sanction guidelines and allows the Secretary to adopt permanent rules (change from original bill).
- Gives the department authority to require fingerprint check-national electronic fingerprint check when state background check is inadequate, for example applicants from another state may have criminal background in jurisdictions other than Washington.
- Authorizes the issuance of a temporary license for those with clear Washington State background check pending national fingerprint check.
- Requires the department to adopt rules requiring license holders to report any criminal convictions with 14 days after conviction.

ACTION: Rosemarie Duffy moved that the Board develop a resolution address to the Secretary of Health expressing the Board's opposition to the shift of authority to the Secretary in initiating mandatory investigations when there is a pattern of conduct. It is not in the best interest of public health and safety. It dilutes the Board's authority and actions will not be taking in a timely manner. The Board has professional staff and the expertise to provide consistency and the Board has historically acted on 30% of our complaints. Susan Teil-Boyer second. **MOTION CARRIED**. 6-0.

SHB1553 – Prescription Monitoring Program – real-time web-based interactive monitoring program to monitor the prescribing and dispensing of Schedule II through V controlled substances. Required department seek federal grants to cover costs to operate the system and prohibits the department from using license fees or taxes specifically designated for the program. (Concept supported by Washington State Pharmacy Association)

SHB1797 – Requires the Methamphetamine Work Group examine the feasibility of electronic reporting of sales of ephedrine, pseudoephedrine and phenolpropanolamine.

SB5631 – Distribution of Drugs – transfers the authority for licensing and inspections of drug wholesalers to the Department of Licensing. Adds definitions that refer to the drug distribution chain for prescription drug and requires the tracking of drugs from the manufacturer to the pharmacy (pedigree). The bill requires wholesalers to submit a security bond of \$100,000. Required the Board of Pharmacy to determine and target the implementation date for an electronic pedigree. (This bill may be dead)

SB1519 – Disclosure of Gifts by Pharmaceutical Manufacturers - Requires the Board of Pharmacy to post disclosure reports on the internet and report to the legislature and Governor.

HB2123 – Exchange of antiepileptic drugs by pharmacies – Prohibits a pharmacist from interchanging antiepileptic drugs for a formulation of an antiepileptic drug brand name or generic for the treatment of seizers without prior consent.

SSB5509 – Modifies the Uniform Disciplinary Act (UDA) on how complaints are handled and requires complaints to be in writing and signed by the complainant. Non-traditional treatment alone is not unprofessional conduct so long as there is no injury and unreasonable risk of harm to the patient. The bill adds definition for false, fraudulent or misleading advertising.

SHB1300 – UDA Changes – Department request legislation. Changes the process for denying applications and allows permanent revocation for egregious violations. Create a citation and fine process to ensure documents are produced in response to requests for investigative purposes.

HB1667 – Health Professions Licensing Fees – amend 43.72.050 establishes a three tier credentialing fee structure for health profession regulated by the department. \$125 licensed professionals, \$50 certified professionals, and \$30 registered professionals.

SB5420 – Public Access to Information – Requires every public agency to post its minutes, rules or resolutions within 15 business days. The bill requires posting the minutes prior to the Board's approval but we would ensure that the minutes are clearly designated as drafts.

<u>Pharmacy Assistants Registration</u> Grace Cheung advised the Board that it can no longer allow pharmacy assistants to work in pharmacies pending application to the state for registration. We have no statutory authority to permit this practice. Initially, the 90 day grace period was granted to allow applicants to complete AIDS training. AIDS training is now more readily available. The department has a responsibility to conduct background checks on all applicants.

We will be providing technical assistance to pharmacies on this change by way of technical assistance during inspections, newsletter article and other means of getting the word out.

The Uniform Disciplinary Act permits temporary licensure for individuals licensed in another state that has licensing standards substantially equivalent to Washington (RCW 18.130.075).

Review Past Board Decisions regarding the practice of pharmacy by off-site pharmacists. Andy Mecca explained that this information is a follow-up his report given in January asking to review past Board decisions in regard to off-site pharmacy practices.

- September 2003 Telepharmacy proposal allowed pharmacist to review orders from a home workstation. *Approved by the Board*.
- June 2006 Pharmacist to perform order entry, drug utilization review and other functions from home. *Approved by the Board*.
- July 2006 Proposal to allow pharmacists to provide drug utilization review. In this proposal the pharmacy was located out of state. *The Board approved the protocol stipulating that the pharmacist must work for a pharmacy licensed in Washington, but did not required the out-of-state pharmacist to be licensed in Washington.*
- December 2006 Proposal for Central fill remote review of prescriptions. *Approved by Board- requiring the drug review take place within a licensed pharmacy not at home.*

Staff Recommendations:

- Permit WA licensed pharmacies to practice pharmacy at an alternative work sites (telecommute).
- Out-of-State off-site practice is allowed when both the pharmacy and pharmacist manager is licensed in Washington. The Responsible manager is accountable for the development and implementation of necessary policies and procedures regarding professional conduct and patient privacy in offsite pharmacy practices.

Questions for Consideration:

- What is different about the December proposal?
- Non-resident mail-order pharmacies shipping into Washington are required to be licensed in this state. What about out-of-state pharmacist that does not engage in mailing prescriptions but practice pharmacy interacting with residents of Washington? The Board authorized this activity, in the past, so long as the pharmacy was licensed in Washington.
- How will the Board discipline an out-of-state pharmacist if not associated with a WA licensed pharmacist?
- Complaint/discipline/investigation coordinated through another jurisdiction?
- Should the Wal-Mart proposal from December 2006 be brought back to the Board?

Doug Beeman, Group Health Cooperative, offered that the practices of pharmacy is changing to include situations where pharmacists working independently or by contract to provide medication management services for patients. Theses pharmacists are not associated directly with a pharmacy.

Dan Connolly – two different types of telepharmacy with different standards - 1) drug utilization review only; and 2) dispensing.

ACTION: Susan Teil-Boyer moved that staff update the guidelines for telepharmacy/remote order processing for review and considerations. Vandana Slatter second. **MOTION CARRIED**. 6-0.

Presentation of Agreed Orders

Business Meeting Adjourned

There being no further business, the Board adjourned at 3:45 p.m. The Board of Pharmacy will meet again on April 12 - 13 in Tumwater, Washington.

Approved on April 12, 2007